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TITLE: Augmentation of Acute Stroke Management Via Telemedicine

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CONTRACTING ORGANIZATION: Walter Reed Army Medical Center
Washington, DC 20307-5001

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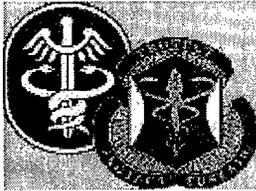
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MidTerm Overall Evaluation Report



PROPOSAL: 2000000040

TITLE: Augmentation of Acute Stroke Management Via Telemedicine

ACCOMPLISHMENTS

ACCOMPLISHMENTS- What have you accomplished relative to the goals as stated in your proposal:

- o Study nurse coordinator started employment at the end of May 2001 to arrange for administrative completion of study associated data collection methods, coordination of installation of study related technical equipment, selecting and ordering equipment, coordination of communication among participating associated investigators, and for patient recruitment.
- o All necessary forms submitted to the IRB. The IRB approval was obtained in August of 2000 with renewal of the protocol in July of 2001.
- o Necessary telemedicine study equipment was installed at the study sites. (PictureTel monitors and associated VTC equipment, flat-screen monitors, one PC, and VCR with digital video tape/VHS capabilities were installed). Investigators received informal and formal training to familiarize themselves with the study equipment.
- o Arranged for installation of lines for transmission of study VTC data, (BRI lines by Verizon for phase I of the study within Walter Reed Army Medical Center from the physician office to the emergency department) Plans are in place for installation of an ISDN for VTC support in the remote site of Dewitt Army Community Hospital, Ft. Belvoir, VA.
- o Installation and functioning personal computer platform for teleradiology with active radiology imaging received from Dewitt Army Community Hospital in the physician home setting using cable modem access and equipment installation by MidAtlantic, Inc. Initiation of similar teleradiology system in the physician office at Walter Reed Army Medical Center has been made.
- o Orientation of associated investigators to relevant skills necessary for the study intervention. Specific information learned included implementation of an acute stroke program, stroke outcomes program, overview of current treatments for stroke, review of diagnostic imaging modalities, and neurological assessment at the bedside.
- o Designing and testing of a database with front-end for entering and retrieving study data for analysis purposes. Testing of running the study database simultaneously with the video teleconferencing (VTC) interface. Based on the development of the database, we are in the process of establishing the feasibility of developing a complementing application for personal digital assistants (PDA) to capture necessary study data during non-VTC bedside assessments. PDA equipment and databases were evaluated, selected and ordered.
- o Completed and refined actual study policies and procedures.
- o Planned abstracts to present and share the outcomes of this current study with the national/international medical community is in progress. This VTC stroke consultation process has been presented already to a military triservice national neurology meeting.

PI's Accomplishment Evaluation: : Project accomplishments are close to proposal

PROBLEMS

PROBLEMS/ISSUES- Identify any problems, internal, external, etc. that have materially affected your project: Delay in installation of technical equipment due to:

- o The single largest delay of the protocol occurred during the protocol review process at Ft. Detrick. The WRAMC IRB approved protocol was provided to the reviewer at Ft. Detrick in mid-January 2001. The review provided some reasonable protocol modification recommendations but these recommendations came very slowly. At one point, the principal investigator had made changes to the protocol within 48 hours of the reviewer's recommendation only to be called the following day with the protocol enroute via mail to make more changes and resubmit the protocol. This process was ongoing until April of 2001, which then the protocol could not be reviewed due to the loss of the quorum at that meeting. A new reviewer for the protocol was assigned and then the protocol received final approval in June 2001, 5 months after initial submission to Ft. Detrick. Clearly, the Ft. Detrick IRB was reviewing a large number of protocols, overwhelming the resources available. Consideration could be made to create additional IRB's to address the large volume of protocol reviews.
- o Long time lapses between the time a written request for equipment ordered and when the equipment actually arrives and is installed at the study sites with the newly added procedure of processing requests via GSA.
- o Defective equipment arrived at the study sites. One PictureTel monitor transmitted images only in green hues. A second flat screen monitor for the teleradiology system did not function properly.
- o A significant delay in hiring supporting research nurse personnel occurred related to the nursing shortage metro area wide in Washington, D.C. This protocol's nurse was not hired until May of 2001.
- o Power outage at WRAMC during the week of 8/27/01 – 8/31/01 causing delay in installation and testing of the technical study equipment. Furthermore, this power outage led to repeated WRAMC server failures diverting key telemedicine personnel to repair the damaged network.
- o The national crisis that occurred on 11 SEP 01 impaired normal business operation at WRAMC and accordingly affected normal communication patterns on post with the outside community. As a result the installation and testing of the technical study equipment was further delayed. Specific example includes the diversion of Department of Information Management (DOIM) at WRAMC from implementing immediately line installation requests.
- o The effects of Internet virus attacks and server crashes at WRAMC, which inadvertently affected the progress of our study. These attacks during the summer continued to divert the resources of DOIM away from this project.

PI's Problem Area Evaluation: : Project encountered some problem/issues

LIFE-CYCLE

SECOND HALF PROJECT LIFE-CYCLE- What are the plans for the second half the project, do they differ from what you stated in your proposal, if so how and why:

- o After installation and testing of all technical equipment and refining of procedures, the plans of the second half of the project are to conduct the practical part, Phase I, of the study and to complete the project as initially proposed. Patients will be recruited, study interventions will be performed, and data will be collected and analyzed.
- o Phase I of the study will be completed as planned; the phase II of the study at the Ft. Belvoir site will be initiated, but complete enrollment of study subjects by the end of the year may not be completed prior to the planned scientific meeting presentation.
- o After data analysis conclusion and recommendation, we will be able to proposed and incorporated into designing a standardized procedure for urgent stroke care as outlined in the initial proposal for this study.

PI's Life-Cycle Evaluation: : Project encountered some problems/issues

DELIVERABLES

DELIVERABLES- What is the final result of the project? will you deliver a study, prototype, paper, system, protocol, etc.? Is the deliverable different from that stated in the original proposal? If so how and why? o The final deliverable product will be a tested new protocol for urgent stroke management with improved patient outcomes. o Differences from the initial proposal will include a more refined method of patient data collection and documentation. (Database on MS Access and a database on a PDA). This computerized system has the tangible benefit of prompting the clinician with predetermined clinical assessment cues. At the same time, diagnostic accuracy and consistency is improved with the aid of such systems. o The advantages of this is that a new system was created as a by-product of this study, which was originally designed to test a new clinical intervention. The deliverables of this proposed study would not only be met but also exceeded. o The bottom line is we believe we will accomplish our goals for an innovative stroke VTC procedure with resultant publication in a peer-reviewed journal.

PI's Deliverables Evaluation: : Deliverable is on schedule per Proposal

Expenditures

| Element of Resource (EOR) | 1ST Quarter Oct 1 - Dec 31 | 2nd Quarter Jan 1 - Mar 31 |
|-------------------------------|-------------------------------|-------------------------------|
| Travel 2100 | \$0.00 | \$2,452.59 |
| Shipping 2200 | \$0.00 | \$0.00 |
| Rent & Communications 2200 | \$0.00 | \$781.52 |
| Contract for Services 2500 | \$112,050.00 | \$16,416.25 |
| Supplies 2600 | \$0.00 | \$150.00 |
| Equipment 3100 | \$704.26 | \$57,664.36 |

Financial Narrative:

FINANCIAL NARRATIVE- This is a text field for use in explaining any deviations in the budget from what was originally proposed.

No significant deviations. Total spending at the end of the financial fiscal year: \$ 218,730.00

PI's Financial Evaluation: : Deliverable is on schedule per Proposal
